



# DANGEROUS SUBSTANCES – LESSONS FROM THE PAST FOR THE FUTURE

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EU2019.FI



# *The European Environment Agency: Informing policy through science*

The EEA is an EU agency that operates at the interface of science and policy.

The EEA provides timely, reliable, targeted and relevant information to support sustainable development.

The Eionet network comprises 1800 experts from over 400 national institutions in 39 countries.



## *Keeping an eye on chemicals*



- European Commission (2001): Global production of chemicals increased 50 times from 1950 to 400 M t in 2001 and is expected to triple again by 2050.
- Chemical industry is Europe's 3rd largest manufacturing industry.
- June 2015: Chemical Abstracts Service (CAS) assigned 100 Millionth CAS Registry Number®.
- Eurostat: about 33 M t of carcinogenic, mutagenic and reprotoxic chemicals produced in 2015 ( ~14% of EU28 chemical production)
- EEA estimated that 62% of the volume of chemicals consumed in Europe in 2016 were hazardous to health

# Europe has REACH but....



- 2020, all known relevant SVHCs are identified, along with possible regulatory measures
- Authorisation and restriction process is seen as an effective driver for substituting SVHCs

**but**

- Compliance with the information requirements by registrants is considered insufficient
- Articles imported to the EU are exempt from the authorisation obligations

*COM/2018/0116 final: COMMUNICATION FROM THE COMMISSION:  
Commission General Report on the operation of REACH and review of certain elements*



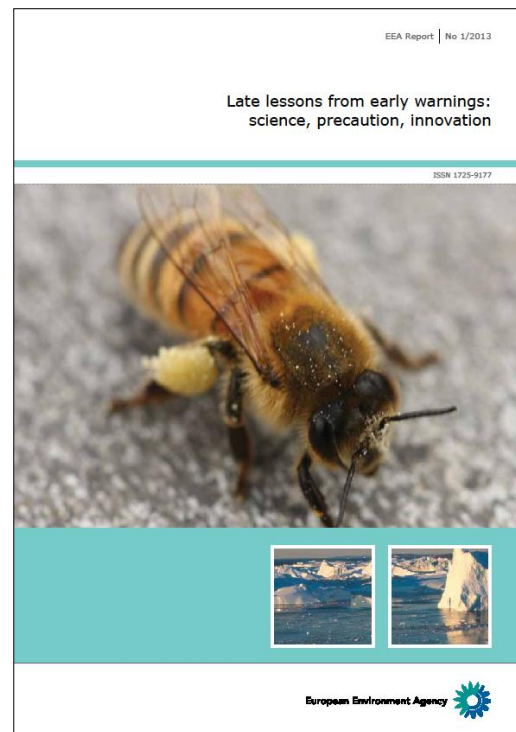
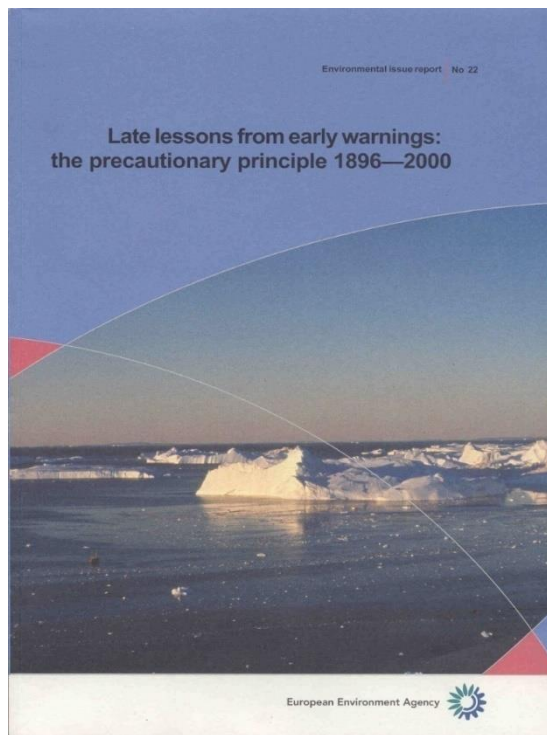
The Eurobarometer study (2016) of almost 28 000 people in 28 countries shows that 65 % are concerned about being exposed to hazardous chemicals, 26% were very concerned.





- The World Health Organization estimated the burden of disease from selected chemicals at 1.6 million lives in 2016 (this is likely to be an underestimate)
- Workplace pollution linked to 0.8 million deaths (*Lancet* Commission on Pollution and Health, Oct 2017)
- Carcinogens account for more than 100 000 work-related deaths (RIVM, 2016)
- Concern for neurotoxicants and substances with endocrine disrupting properties

# Late lessons from early warnings : 2001 and 2013



# Delays between early warning and actions

**Asbestos:** 1929 asbestosis; 1954 lung cancer; 1959 mesothelioma;

## Major steps, workplaces and market restrictions

**EU 1980 Work places:** Protection of workers from the risks related to exposure to chemical, physical and biological agents at work: *'Exposure to workers to agents be avoided or kept as low a level as is reasonably practical'* (80/1107/EEC)

**EU 1983 Work places:** Directive on the protection of workers from the risks related to exposure to asbestos at work: Ban of certain types of spraying, OEL: 1 fibre/ cm<sup>3</sup> introduced (83/477/EEC)

**EU 1985 Market restriction:** Ban of placing on the market and use of products of asbestos in several uses: toys, materials applied by spraying, retail products in powder form, smoking accessories, catalytic heaters, paints/ varnishes (85/610/EEC)

**EU 1991 Work places:** OEL reduced to 0.6 fibre/cm<sup>3</sup> for white asbestos, chrysotile (91/382)

**EU 1991 Market restriction:** Banned of 5 types and 14 uses of asbestos, particularly in construction materials (91/659/EEC)

**EU 1999 Market restriction:** banned all uses of all asbestos types with few exceptions; transposition to MS latest Jan 2005 (1999/77)

**EU 2003 Work places:** OEL set at 0.1 fibre/cm<sup>3</sup> for chrysotile, detailed regulations for protection (2003/18/EC)

**EU 2006 Market restriction:** Ban of production and use (one exception), also for chrysotile (REACH Annex XVII)

**EU 2009 Work places:** Directive on the protection of workers from the risks related to exposure to asbestos at work. Latest regulation for workplaces, all uses prohibited, detailed regulations for removal and demolition work, OEL set at 0.1 fibre/cm<sup>3</sup> etc. (2009/148/EC)

# *Delays between early warning and actions*

**Lead: early warnings** in 1925, 1979 brain damage in children; 2012 heart disease in adults→

In Europe, the **Aarhus Protocol (UNECE, 1998)** initiated the phase-out of leaded petrol,  
**EU 2000 End-of-life-of-vehicles**, sector specific lead restrictions  
**EU REACH 2006 (Annex XVII)**, manufacture and market restriction

## **Major steps, workplaces**

**EU 1980 Workplaces:** Protection of workers from the risks related to exposure to chemical, physical and biological agents at work: 'Exposure to workers to agents be avoided or kept as low a level as is reasonably practical'.

**Lead and compounds as substances with strongest protection measures** (80/1107/EEC)

**EU 1998 Workplaces:** Risks related to chemical agents at work of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

**Binding EU limit value for inorganic lead and compounds**, 0,15 mg/m<sup>3</sup> (Chemical Agents Directive, 98/24 EC)

# OSH legislation nowadays

24 EU OSH Directives, among which:

- **Framework Directive (Directive 89/391/EC), sets out the principles**
- **Chemicals (Directive 98/24/EC)**
  - Sets out principles, e.g. workplace risk assessment
  - Hierarchy of control measures – elimination and substitution, technical and organisational measures and, as a last resort, personal protective measures
  - Health surveillance, information and participation of workers
- **Carcinogens and Mutagens (Directive 2004/37/EC)**
  - More stringent measures for carcinogens and mutagens (e.g. closed system, and delimitation of areas where they are used, etc.)
  - Directive (EU) 2017/2398, introduced 11+2 binding OELs
  - Directive (EU) 2019/130, introduced 6 binding OELs
  - Directive (EU) 2019/983, introduced 5 binding OELs



## ***Delays between early warning and actions***

- **PCBs: 1960s** bird reproduction; 2000s neurological harm in children, soil contamination→ **1996 EU directive to eliminate PCBs by 2010**
- **Mercury: 1950 neurological effects**; 1960s birth defects; 1990s children's IQs fall→ The **Minamata Convention entered into force in 2017.**

## *Reasons for the delays: lack of knowledge and ambiguity*

### **Knowledge deficit:**

Unknown effects: asbestos causing mesothelioma

Unknown exposure routes: methylmercury through fish consumption

Unanticipated consequences: persistent cyclic siloxanes are measured in arctic air samples

**Microplastics ? Nanoforms ?**

### **Ambiguity:**

Dissent across disciplines: toxicologists versus epidemiologists and EDCs

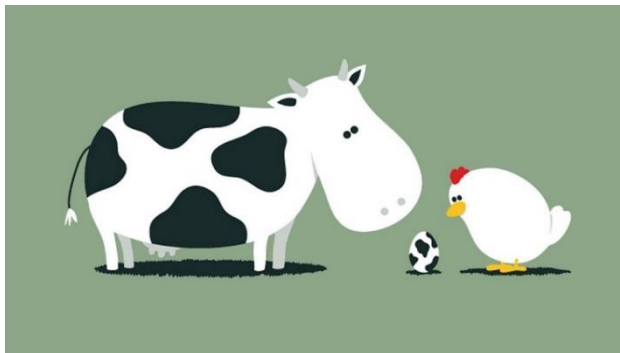
Vested interests: tobacco, adding tetraethyl lead to petrol

**Bisphenol A: risk assessments with different conclusions**

**Glyphosate: risk assessments from EFSA and IARC had different conclusions**

## *Reasons for the delay: uncertainty*

High strength of evidence required to establish scientific causality  
High burden of proof needed for action ↔ precautionary principle?



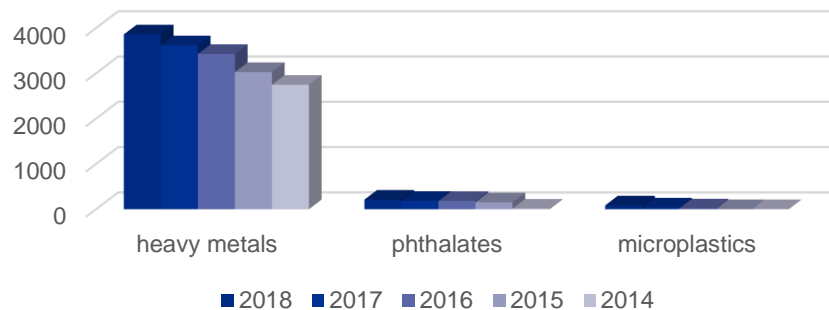
*all scientific work is incomplete—where it be observational or experimental,’ noting that this uncertainty ‘does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time’*

Bradford Hill, 1965

## Reasons for the delay: inertia in science

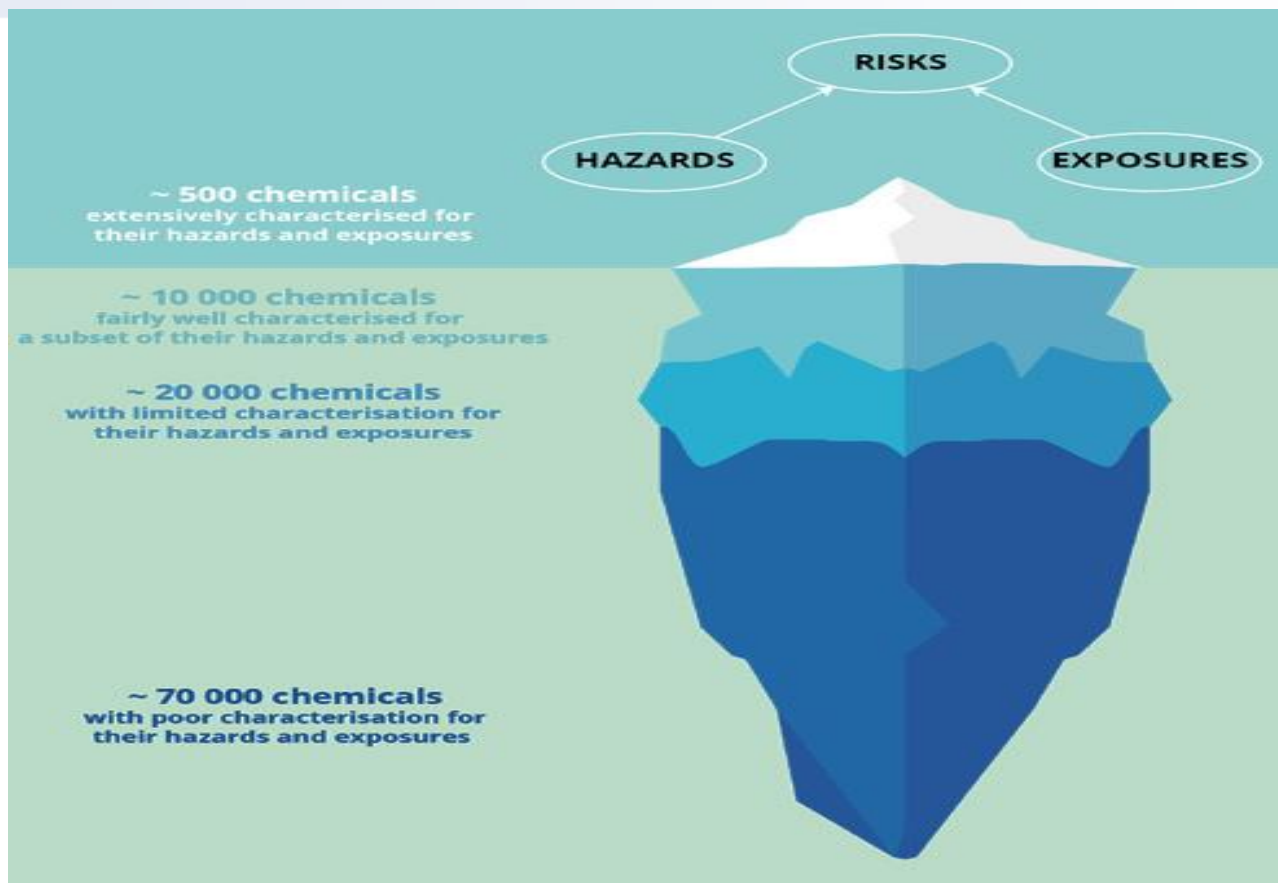
Too many studies on too few chemicals: in depth research

Results per year: compound x health  
(Pubmed)



Exploring new and emerging risks: horizon scanning

## *Monitoring for a wider variety of chemicals can provide earlier warnings*



# *Research and governance are challenged by the speed of development*



## Per/polyfluorinated compounds (PFASs)

General population + firefighters, ski-waxers and workers in fluorochemical plants

First surveys (OECD) in 2004- only PFOS and PFOA  
Now: more than 4700 known PFAS

**1% of the total amount that EU Framework Programmes of Research and Development (2002-2013) allocated to developing products from nanotechnologies, biotechnologies and ICT was spent researching their potential hazards**

<https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/productionandemissions/>

### What are the effects of combined low exposures ?

Something from 'nothing' and 'a lot from a little'



Thrupp et al. *Sci Total Environ.* 2018 Apr 1;619-620:1482-1492. doi:10.1016/j.scitotenv.2017.11.081.

## ***Complexity II: the hazards were shown over time to be more diverse and widespread than first anticipated***



**Same chemical**  
→ **Different effects**  
→ **Different thresholds**

### **Same chemical, different exposure routes**

Plastic toys

Food packaging and drink bottles

Indoor pollution

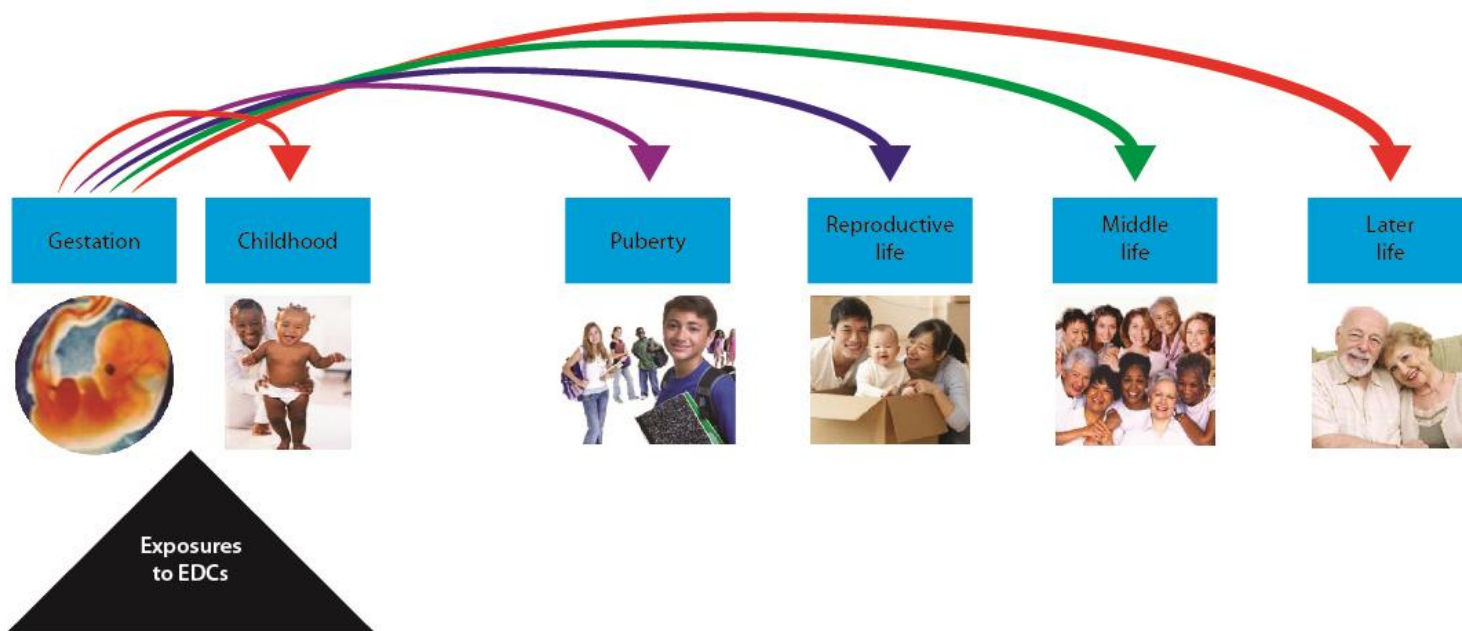
Soil contamination

Work places

→ **Exceeds one policy domain**

## Complexity III: sensitive windows of exposures

Developmental exposures at the start of life may lead to adverse health effects later in life



## Complexity IV: Transgenerational effects?



- Vinclozolin
- DES
- Methoxychlor
- Bisphenol A
- Dioxin
- Phytoestrogens
- Heavy metals
- Tributyltin
- Cigarette smoke

ENVIRONMENTAL



EPIGENETICS

# ***Capturing the systemic dimensions of risks***



## **EFSA's MUST-BEE Project:**

The development of a holistic approach for the risk assessment on multiple stressors in bees

- Viruses
- Neonicotinoids
- Fragmentation of the habitat
- Climate change

## *Evolving environmental challenges: from specific to systemic*

<b>Characteristic</b>	<b>Process</b>	<b>examples</b>
<b>Specific</b> 1970s/1980s (continuing today)	<b>Single actor – single substance</b>	<b>Compliance with occupational exposure limits for single chemicals (OEL)</b>
<b>Diffuse</b> 1980s/1990s (continuing today)	<b>Cumulative causes Multiple sources Regional</b>	<b>Biomechanical, physical, and chemical hazards in agricultural workers Exposures of workers' families</b>
<b>Systemic</b> 1990s/1990s (continuing today)	<b>Interlinkages Global level</b>	<b>Exposures of workers in the circular economy</b>



## Changing the risk assessment paradigm

Reductionist approaches  
Linear relationships  
One chemical, one effect  
Deterministic or probabilistic risk assessment

Combine data from different media

Monitor aggregated exposures

Grouping of chemicals to speed up and avoid regrettable substitution



## *Changing the risk assessment paradigm: early warnings*

Use early warnings signals in different media from a wide variety of chemicals to inform risk framing

Prioritise and focus on critical parameters instead of gathering more general data)



## ***Changing the risk governance: broaden the impact assessment***

Include long-term impacts (late effects)

## Include vulnerable populations

Consider distribution of costs and benefits within the society

Include externalities in pricing (damage across boundaries)



## *Changing the risk governance: manage systemic risks*

World wide networking: fluid borders, global transport and economies:

Obtain non toxic material cycles

Reduce and minimize the use of hazardous che



## Changing the risk governance: speeding up and innovate



Better use of information on hazards and persistency in the design phase of products

→ “*safe-and-circular-by-design*”

Better balance between innovation in chemicals with potential risks

Consider up-front future liability

More funding for alternatives

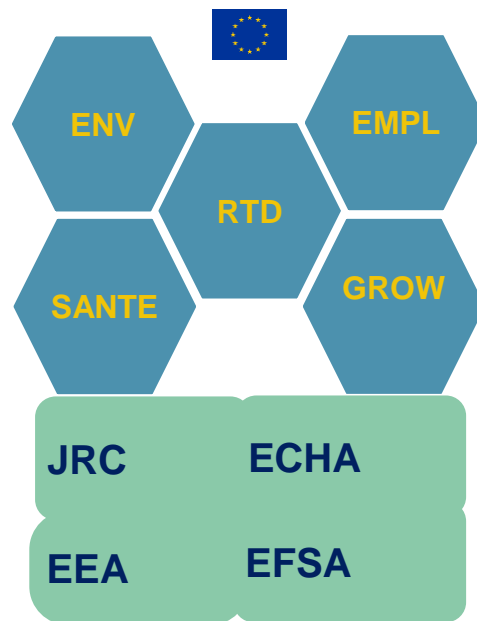
Current financial models benefit more short term profits than profits from innovation



### Co-creation of knowledge

- Broaden the quality of the knowledge base
- Harmonise chemicals legislation across media, substances and their use
- Foster cross policy agendas

#### EU policy board



# Changing the risk governance: create a visionary and inclusive stakeholder approach

- Co creation between industry, scientists and regulators to increase

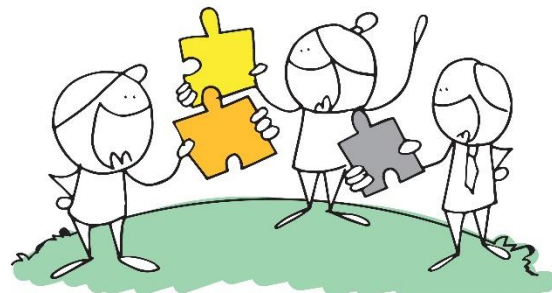
- Accountability

- Trust

- Transparency

- Wide acceptance of risk management measures

- Include all available knowledge
- Include different perceptions and concerns
- Capture societal values to inform framing and trade of
  - Declare all vested interests
  - Document procedures and methods
  - Report uncertainties



- Better access to information, enhance public awareness of exposures



## ***Conclusion:***

**In 2002 the EU agreed “to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment”**

World Summit on Sustainable Development” 2002



**2019: Ursula von der Leyen, President of the European Commission has promised a European Green Deal, including the ambition of moving towards zero-pollution.**

*Thank you!*

